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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Miscellaneous Products	**Original Policy Date:**	November 4, 2016
Subject:	Evzio	**Page:**	1 of 4

Last Review Date: June 16, 2022

Evzio

Description

Evzio (naloxone injection)

Background
Evzio (naloxone) is a single-use auto-injector that contains naloxone hydrochloride. Naloxone is an opioid antagonist that directly counteracts the effect of opioid medications by competing for the same drug receptors. In cases of opioid drug overdose, this competitive inhibition helps reverse the depressant effects of opioid agonists. Opioid reversal is key in turning back the respiratory depression, CNS sedation, and low blood pressure associated with opioid overdose (1-2).

Regulatory Status
FDA approved indication: Evzio is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

1. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present.
2. Evzio is not a substitute for emergency medical care (1-2).

Evzio is approved to use in anyone of any age that is suffering from suspected or known opioid overdose with slight differences in the technique used for administration based on the age of the patient (1-2).

Related policies

LifEMS Naloxone

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Evzio may be considered **medically necessary** in an auto-injector formulation for the treatment of patients with suspected or known opioid overdose or high risk of suspected opioid overdose and if the conditions indicated below are met.

Evzio may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Emergency treatment for suspected or confirmed opioid overdose

2. High risk of suspected opioid overdose

AND ALL of the following:

a. Inadequate treatment response, intolerance, or contraindication to **ALL** of the following:
    a. Narcan nasal spray
    b. Generic naloxone (vials)
    c. Generic naloxone (auto-injector, prefilled syringe, or solution cartridge)

Prior – Approval Renewal Requirements

Same as Above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity and Duration
0.4mg	1 carton (2 auto-injectors) per 180 days **OR**
2mg	1 carton (2 auto-injectors) per 180 days

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Opioid receptor antagonists have respiratory and CNS depression reversal properties for opioid overdose. Evzio is FDA-approved for the reversal of known or suspected opioid overdose by competitive antagonism of key receptors in patients of any age. Naloxone is a pregnancy category B drug that should be used only in cases of clear benefit. The safety and efficacy of naloxone have been established in pediatric patients with numerous clinical studies as well as post-marketing data and clinical practice guidelines (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Evzio while maintaining optimal therapeutic outcomes.

References

1. Evzio 0.4mg [package insert]. Richmond, VA, Kaleo Inc.; April 2014.
2. Evzio 2.0 mg [package insert]. Richmond, VA, Kaleo Inc.; October 2016.

Policy History

Date	Action
November 2016	New addition to PA
January 2017	Addition of 2mg strength to approval limits
June 2017	Annual editorial review and reference update
June 2018	Annual editorial review

June 2019	Annual review
March 2020	Addition of requirement to t/f generic naloxone auto-injector
June 2020	Annual review
March 2021	Annual editorial review
December 2021	Annual review. Per FEP, addition of prefilled syringe and solution cartridge to generic naloxone formulations the patient must have inadequate response, intolerance, or contraindication to.
March 2022	Annual review
June 2022	Annual review

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.